



# BRS Stakeholder Update



**Winter 2007-2008**

Message from the Deputy Administrator

Hello! I'm Michael Gregoire, the new Deputy Administrator for the Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services' (BRS) program. You may not recognize my name, but I look forward to getting to know many of BRS' stakeholders in the coming months.

Rebecca Bech departed BRS on January 7<sup>th</sup> to become the Deputy Administrator of APHIS' Plant Protection and Quarantine (PPQ) Program. Dr. Ric Dunkle, recently retired from this position. Rebecca began her career with APHIS in 1986 as a PPQ officer. This, coupled with the fact that BRS works so closely with PPQ on many issues of mutual concern, makes it a nice fit for her. Rebecca has made a significant impact on BRS and we wish her the best in her new and important role within APHIS.

It is an honor for me to serve with the dedicated and hard working staff in BRS. They have faced many challenging tasks over the years and I look forward to coupling my experience with theirs to tackle new issues in the future. I will continue to work closely with Rebecca as well as APHIS Administrator Cindy Smith to ensure a smooth transition and minimize any disruptions in the delivery of our program mission. I began my Federal career as a budget analyst with APHIS in 1978 and served in various positions and programs over the years. I was appointed Deputy Administrator for Policy and Program Development in March 2005, and provided leadership and guidance for the Agency in the areas of planning, policy development, budgeting, regulatory decision-making, and compliance with environmental statutes and regulations. In my new role as BRS Deputy Administrator, I look forward to working together with our stakeholders to ensure the safe development and introduction of genetically engineered organisms. One of my initial priorities is to talk with stakeholders to understand their issues and share BRS' priorities and goals.

I'd now like to provide you with an update on BRS' endeavors over the past several months. We hope you find this stakeholder update informative, and encourage you to visit our Web site (<http://www.aphis.usda.gov/biotechnology>) for the latest news and information. If you have not previously registered with our on-line BRS stakeholder registry, please go to <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf> and sign up to ensure that you receive all future stakeholder updates.

Sincerely,

Michael Gregoire  
BRS Deputy Administrator

NEPA Changes

As noted in the Summer 2007 edition of the BRS Stakeholder Newsletter, BRS recently modified its National Environmental Policy Act (NEPA) implementing procedures to ensure that we are

developing consistent and comprehensive assessments for each application. In addition, BRS is strengthening its procedures to further its compliance with provision in the Endangered Species Act. With spring planting dates quickly approaching, BRS is currently receiving large numbers of notification and permit applications daily. BRS is again requesting that all applicants submit their applications as soon as possible to allow BRS the maximum amount of time to complete the appropriate analyses. Due to the large volume of applications and improved processes, BRS depends on the timeliness and completeness of applications during this period to meet its regulatory and performance objectives. Applications will be handled in the order that they are received and every effort will be made to review and approve applications prior to the necessary effective date.

For those applicants submitting permits that may require an environmental assessment, please contact BRS as soon as possible to discuss timelines in more detail.

### BRS Seeks Public Comment on Genetically Engineered Alfalfa

On January 7, 2008, BRS published a notice in the *Federal Register* seeking public comment to shape the scope of an environmental impact statement (EIS) to assist in the determination of the status of genetically engineered (GE) Roundup Ready (RR) alfalfa under APHIS biotechnology regulations. Due to a court order, we will prepare the EIS to evaluate potential environmental effects of deregulating the GE alfalfa. We have identified 18 issues that will be studied in the EIS, including impacts on food and feed, U.S. trade, and threatened and endangered species. We are seeking public comment to identify other issues that also should be addressed in the EIS.

In 2003, the Monsanto Company and Forage Genetics International submitted a petition requesting nonregulated status for RR alfalfa lines J101 and J163. APHIS prepared an environmental assessment (EA) to determine whether deregulating the alfalfa, genetically engineered to resist the herbicide glyphosate (known commercially as Roundup), could have a significant impact on the environment. After a thorough review of the scientific evidence, we issued a finding of no significant impact and deregulated the lines on June 14, 2005. We make a determination of nonregulated status only when we can conclude that the organism does not pose a plant pest risk.

To comply with a judgment and order by the United States District Court for the Northern District of California, we now must prepare an EIS in support of our 2005 decision to deregulate RR alfalfa. The court did not overturn federal conclusions regarding the safety of the crop for food and feed purposes, but rather concluded that we had not adequately documented potential, or lack of potential, environmental impacts. On March 23, 2007, APHIS published a *Federal Register* notice announcing that RR alfalfa was once again a regulated article. A future decision regarding the deregulation of RR alfalfa will be issued only after the completion of the appropriately documented EIS.

The *Federal Register* notice can be viewed, and comments can be submitted at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0044>. Consideration will be given to comments received on or before Feb. 6.

### BRS Enters into Cooperative Agreement with AOSCA on Isolation Distances

BRS has entered into a cooperative agreement with the Association of Official Seed Certifying Agencies (AOSCA) to examine the adequacy of established isolation distances for rice, cotton,

alfalfa, corn, wheat, and safflower. BRS currently bases its isolation distances on AOSCA standards for seed purity.

AOSCA will prepare scientific papers after reviewing literature regarding outcrossing and the efficacy of isolation distances for these crops, as well as evaluating the basis for establishing isolation distances used in its seed certification standards and the acceptable levels of off-types permitted in certified seed. This information will be useful for BRS to determine if AOSCA methodologies for meeting seed standards and assuring these standards are met could be adopted to meet BRS field-testing permit standards. Understanding the effectiveness of tolerance standards for achieving seed purity would also be useful to BRS, as we have already begun examining rice isolation distances.

### BRS Concludes Genetically Engineered Creeping Bentgrass Investigation

On November 26, 2007, BRS announced the conclusion of its investigation into alleged compliance infractions by The Scotts Company, LLC, related to regulated genetically engineered (GE) glyphosate-tolerant creeping bentgrass. Under a settlement agreement, Scotts agreed to pay a civil penalty of \$500,000—the maximum penalty allowed by the Plant Protection Act of 2000. This is a severe civil penalty and underscores BRS' strong commitment to compliance with its regulations. Scotts also agreed to conduct three public workshops within 1 year to present best management practices and technical guidance for other potential developers of GE plants, and all other interested parties, on the identification and prompt resolution of biotechnology compliance incidents. The allegations address the ongoing persistence in the environment related to the accidental release of the regulated GE glyphosate-tolerant creeping bentgrass.

BRS entered into this settlement agreement with Scotts to resolve allegations that the company failed to comply with performance standards and permit conditions for field trials of glyphosate-tolerant creeping bentgrass and improperly moved GE grass seed. Scotts already has implemented measures to comply with performance standards and permit conditions related to these allegations. In addition, BRS alleges that Scotts failed to conduct a 2003 Oregon field trial in a manner which ensured that neither glyphosate-tolerant creeping bentgrass nor its offspring would persist in the environment. Scotts currently is taking monitoring and mitigation actions in Oregon to locate and remove the regulated GE material that was accidentally released during the 2003 field trial. These actions were required by BRS beginning in 2004 to address past allegations that Scotts failed to notify BRS of the 2003 accidental release.

### BRS Announces Biotechnology Quality Management System

On September 20, 2007, BRS announced a new program to help universities, small businesses, and large companies develop sound management practices to enhance compliance with regulatory requirements for field trials and movements of GE organisms. The new Biotechnology Quality Management System (BQMS), a voluntary compliance assistance program, is scheduled for initial implementation via a pilot program in spring 2008.

BQMS complements a program called, "Excellence Through Stewardship," which is already underway in the biotechnology industry. While industry's program is focused on quality management to ensure product integrity of biotech-derived plant products throughout the product life cycle, BRS will emphasize the quality of the process for safely introducing these GE organisms in compliance with federal regulations.

BRS will oversee BQMS in partnership with USDA's Agricultural Marketing Service (AMS), which will manage the audit component of the program and accredit third party auditors. Audits will verify that participants have procedures in place, and that they are performed correctly to meet the regulatory requirements for any given GE field trial or movement. As part of the program's emphasis on preventive measures, participants will be encouraged to correct deficiencies discovered in an audit before compliance problems develop. BQMS and its associated audits will complement, not replace, BRS' current regulatory compliance and inspection process by focusing on planning and good management practices that can improve a participant's ability to meet regulatory requirements.

### USDA Concludes Genetically Engineered Rice Investigation

On October 5, 2007, BRS announced the conclusion of its GE rice investigation, which focused on the unintentional release of trace amounts of regulated GE rice detected in two commercial varieties of long-grain rice. The investigation involved more than 8,500 staff hours and site visits to more than 45 locations in 11 states and Puerto Rico.

Bayer CropScience developed and field tested the regulated GE rice lines known as LLRICE601 and LLRICE604, which were designed for herbicide tolerance. Both GE rice lines have the same added protein, commonly referred to as the PAT protein, which has been safely used in other deregulated products for more than ten years.

As a result of this extensive sampling, investigators determined that the presence of LLRICE601 was limited to Cheniere and that the presence of LLRICE604 was limited to CL131. In both cases, only trace amounts of GE material were present. No short- or medium-grain rice varieties tested positive for either LLRICE601 or LLRICE604. Investigators had hoped to identify how each GE rice line entered the commercial rice supply, but the exact mechanism for introduction could not be determined in either instance.

Based upon the findings of the investigation, BRS will not be pursuing enforcement against Bayer CropScience. Given the lack of available information and evidence, BRS was unable to make any definitive determinations that could have resulted in enforcement action.

BRS released a report of the findings as well as lessons learned from this and other investigations and from its experience as regulators. For example, BRS is considering establishing retention requirements for records. BRS also is considering greater isolation distances between seed breeding fields and GE varieties in order to reduce the likelihood of pollen flow.

### Clarification of policy on perennials and multi-year notification

BRS is clarifying its policy regarding the authorization of environmental releases of certain GE organisms when the release is intended to last for more than one year. Based upon accumulated regulatory experience and currently available science, BRS is discontinuing the practice of acknowledging notifications for all environmental releases lasting longer than one year. Our experience shows that multiyear field tests can pose special challenges with respect to meeting the performance standards for notifications. Thus, in order to provide the enhanced administrative oversight that is needed, all releases intended to last more than one year, including releases of perennials, biennials, and annuals left in the ground for more than 365 days, may only be authorized by permit, and not by notification.

All field tests under acknowledged notifications must be terminated within one year from the date of the introduction, or before the expiration date of the acknowledged notification, whichever comes first. Further, “renewals” by means of a notification to extend the duration of the release period authorized by a prior acknowledged notification will no longer be acknowledged. Perennial and biennial species may still be grown under an acknowledged notification, so long as that release is fully terminated no later than one year from the date of introduction. All other releases of perennial and biennial species must be authorized under a permit and not under a notification.

Responsible parties who currently hold an acknowledged notification having a duration of more than one year must reapply for authorization under permit. BRS will terminate all such multi-year notifications on September 10, 2008. If such releases are to continue beyond that date, responsible parties must apply for a permit no less than six months prior to the current expiration of the acknowledged notification or September 10, 2008, whichever comes first.

For those current releases of perennials or biennials authorized under notifications that will expire before March 10, 2008, if the responsible party wishes to continue the introduction beyond the termination date, APHIS may authorize the continued release under a new, non-renewable notification solely for the purpose of allowing the responsible party sufficient time to acquire a valid permit. For responsible parties who intended to release perennials or biennials under notification before March 10, 2008, and who have not yet submitted a notification, APHIS may similarly authorize the release under a non-renewable notification to allow sufficient time to acquire a valid permit.

#### Policy Clarification on *Drosophila* Courtesy Permit Applications

BRS issues courtesy permits for non-regulated organisms upon request in order to facilitate their movement, which might otherwise be impeded because of the similarity of the organism to other regulated organisms. Recently, shipments manifested as “fruit flies” have raised agricultural and environmental concerns because this common name also refers to plant pests like the Mediterranean and oriental fruit flies.

In the past, BRS has accepted courtesy permit applications for importations of non-regulated *Drosophila* that were based upon a template of a partially-completed APHIS Form 2000. As of January 1, 2008, applications based upon this template will no longer be accepted to issue a courtesy permit. BRS is requiring applicants requesting a courtesy permit for *Drosophila* importations to apply through ePermits or to fully complete and submit an APHIS Form 2000 with all required information, including details of the inserted construct. This information is necessary for BRS to confirm that the transgenic *Drosophila* are not regulated articles before issuing a courtesy permit.

#### ePermits Update

BRS recently implemented the ability to upload permits into ePermits via XML upload. Applicants with internal databases can now upload data from their database into ePermits without needing to manually enter data into the standard webforms. We hope our applicants find this new tool useful and time saving!

## BRS Participates in Biotechnology Risk Analysis Symposium

On December 5-6, 2007, BRS participated in the 2<sup>nd</sup> Symposium for Agricultural Biotechnology Risk Analysis Research in College Park, MD, as part of an effort to facilitate dialogue between federally-funded investigators and the scientists and administrators responsible for regulatory oversight of agricultural biotechnology products. The symposium was sponsored by previous members of the Agricultural Biotechnology Risk Analysis Research Task Group (AGRA), an interagency task group that included USDA, the Food and Drug Administration, the Environmental Protection Agency, the U.S. Geological Survey, and the U.S. Agency for International Development, among others. The meeting provided an opportunity to expand the dialog between BRS and the researchers involved in research related to agricultural risk analysis.

## BRS Employee Spotlight

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

**Employee:** Emily Pullins

**Position:** Chief, Compliance and Inspection Branch, Regulatory Operations Division

**Years with BRS:** 2 – I joined BRS in August 2004, and was here for 18 months as a Compliance Office in CIB. Then, I spent one year at the APHIS Investigative and Enforcement Services as an Enforcement Specialist. During that time, I was assigned to provide support services on BRS program investigations. As of this summer, I was hired by BRS as the Supervisory Biotechnologist for the Compliance and Inspection Branch within the Regulatory Operations Division.

**Activities prior to joining BRS:** I worked for four years as a post-doctoral candidate working on sustainability science and biosafety science initiatives at the University of Minnesota.

**Education:** I have a B.A. in biology from University of California, an M.S. in Agronomy and Plant Genetics from the University of Missouri, and a Ph.D. in Agronomy and Plant Genetics from the University of Minnesota.

**Job Description:** I am responsible for overseeing a program that simultaneously provides compliance assistance, assurance, and enforcement.

**Proudest Accomplishment:** There have been *many* significant milestones and innovations in the history of the Compliance and Inspection Branch in the past three years that I have been proud to play a role in. Most recently, I am proud of the formation of a compliance assistance function in our branch, initiated by the development of the Biotechnology Quality Management Program.

**What motivates you about your job:** I feel that this is an important moment in the history of a revolutionary scientific and technical innovation. My primary motivation is to bring ingenuity and lessons learned from history to bear on biotechnology in a way that maximizes discovery while minimizing any negative impacts.

### Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting <http://jobsearch.usajobs.opm.gov/> and searching for “Biotechnology Regulatory Services” (in quotes).

#### **Total 2007 Submissions**

##### Notifications Acknowledged

202	Importation
338	Interstate Movement
246	Environmental Release
589	Combined Interstate Movement/Release

##### Permits Issued

18	Importation
47	Interstate Movement
25	Environmental Release
747	Courtesy Permits

4 Petitions/Extensions to Grant Non-Regulated Status Received

Have questions about BRS policy and regulations? E-mail us at [biotechquery@aphis.usda.gov](mailto:biotechquery@aphis.usda.gov)